

1. A method for administering a corticosteroid to a patient, comprising implanting a sustained release drug device in a posterior segment of an eye of said patient, said drug delivery device comprising;
  - (i) an inner core including one or more corticosteroids to be released;
  - 5 (ii) an impermeable coating which is impermeable to the passage of said corticosteroid(s) and including one or more pores through which said corticosteroid(s) diffuse, said impermeable coating being essentially insoluble and inert in body fluids, and compatible with eye tissues; and
  - 10 (iii) one or more permeable coatings which are permeable to the passage of said corticosteroid(s), said permeable coatings being essentially insoluble and inert in body fluids, and compatible with eye tissues;wherein said impermeable and permeable coatings are disposed about said inner core so as to produce, when implanted, a constant release of said corticosteroid(s) from said device at a rate that is not dependent on the rate of dissolution of the inner core, and which does not result in toxic amounts of the corticosteroid(s) accumulating in the aqueous humor of the eye.
- 15 2. The method of claim 1, wherein said device is implanted intravitreally.
- 20 3. The method of claim 2, wherein the vitreous corticosteroid concentration is less than 10 µg/ml.
4. The method of claim 1, wherein during release of the corticosteroid(s), the aqueous humor corticosteroid concentration is non-toxic.
- 25 5. The method of claim 4, wherein the aqueous humor corticosteroid concentration is less than 0.05 µg/ml.
6. The method of claim 1, as part of treatment or prevention for a disease state selected from the group consisting of ocular neovascularization, ocular inflammation, retinal degeneration, and retinopathy.
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7. The method of claim 1, for delivering said corticosteroid(s) to the retina, retinal pigment epithelium (RPE) or choroids of the eye.
- 5 8. The method of claim 1, wherein said corticosteroid is selected from triamcinolone, dexamethasone, cortisone, prednisolone, flumetholone, and derivatives thereof.
9. The method of claim 1, wherein said corticosteroid is fluocinolone.
- 10 10. The method of claim 1, wherein said corticosteroid is fluocinolone acetonide.
11. The method of claim 1, wherein said corticosteroid is loteprednol.
- 15 12. The method of claim 4, wherein said corticosteroid is fluocinolone.
13. The method of claim 4, wherein said corticosteroid is fluocinolone acetonide.
14. The method of claim 4, wherein said corticosteroid is loteprednol.
- 20 15. The method of claim 6, wherein said corticosteroid is fluocinolone.
16. The method of claim 6, wherein said corticosteroid is fluocinolone acetonide.
- 25 17. The method of claim 6, wherein said corticosteroid is loteprednol.
18. The method of claim 1, wherein release of said corticosteroid(s) from said device follows zero order kinetics for at least 100 days.
- 30 19. The method of claim 1, wherein said sustained release device has a mean release rate for said corticosteroid(s) of 1  $\mu\text{g/day}$  to 50  $\mu\text{g/day}$ .

20. The method of claim 14, wherein said sustained release device has a mean release rate for said corticosteroid(s) of 1 µg/day to 10 µg/day.

5 21. The method of claim 1, wherein said constant release of said corticosteroid(s) includes a linear release of said corticosteroid(s) for at least 100 days.

22. The method of claim 1, wherein said device releases said corticosteroid(s) for 1 month to about 20 years.

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23. The method of claim 1, wherein said device releases said corticosteroid(s) for 6 months to 5 years.

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24. The method of claim 1, wherein said permeable coating(s) comprises a polymer coating selected from polyvinyl alcohols; polyolefins; polyvinyl chlorides; cross-linked gelatins; insoluble, non-erodible cellulose; polyurethanes; polycarbonates; and microporous polymers formed by co-precipitation of a polycation and a polyanion modified insoluble collagen.

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25. The method of claim 1, wherein said permeable coating(s) comprises polyvinyl alcohol.

26. The method of claim 1, wherein said impermeable coating comprises ethylene vinyl acetate.

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27. The method of claim 1, wherein said impermeable coating comprises polyvinyl acetate.

28. The method of claim 1, wherein said impermeable coating comprises polyimide.

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29. The method of claim 1, wherein said impermeable coating comprises a silicone polymer.
30. The method of claim 1, wherein said pores in said impermeable coating of said device are less than 25 % of the surface area.
31. The method of claim 1, wherein said pores in said impermeable coating are less than 5 % of the surface area.
32. The method of claim 1, wherein said pores in said impermeable coating are less than 1 % of the surface area.
33. The method of claim 1, wherein said sustained release device is attached to an intraocular lens or the haptic extending from said intraocular lens.
34. The method of claim 1, as part of treatment or prevention for a disease state selected from the group consisting of: diabetic retinopathy; chronic glaucoma; retinal detachment; sickle cell retinopathy; senile macular degeneration; retinal neovascularization; subretinal neovascularization; rubeosis iritis inflammatory diseases; chronic posterior and pan uveitis; neoplasms; retinoblastoma; pseudoglioma; neovascular glaucoma; neovascularization resulting following a combined vitrectomy and lensectomy; vascular diseases retinal ischemia; choroidal vascular insufficiency; choroidal thrombosis; neovascularization of the optic nerve; diabetic macular edema; cystoid macular edema; macular edema; retinitis pigmentosa; retinal vein occlusion; proliferative vitreoretinopathy; angiod streak; and retinal artery occlusion.
35. An implantable, sustained release device for administering a corticosteroid to a posterior segment of an eye, said device comprising:
- (i) an inner core including one or more corticosteroids to be released;

(ii) an impermeable coating which is impermeable to the passage of said corticosteroid(s) and including one or more pores through which said corticosteroid(s) diffuse, said impermeable coating being essentially insoluble and inert in body fluids, and compatible with eye tissues; and

5 (iii) one or more permeable coatings which are permeable to the passage of said corticosteroid(s), said permeable coatings being essentially insoluble and inert in body fluids, and compatible with eye tissues;

wherein said impermeable and permeable coatings are disposed about said inner core so as to produce, when implanted, a constant release of said corticosteroid(s)  
10 from said device at a rate that is not dependent on the rate of dissolution of the inner core, and which does not result in toxic amounts of the corticosteroid(s) accumulating in the aqueous humor of the eye.

36. The device of claim 35, dimensioned for intravitreal implantation.

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37. The device of claim 35, wherein the rate of release of said corticosteroid(s) produces a vitreous corticosteroid concentration of less than 10 µg/ml.

38. The device of claim 35, wherein the rate of release of said corticosteroid(s)  
20 produces an aqueous humor corticosteroid concentration that is non-toxic.

39. The device of claim 38, wherein the aqueous humor corticosteroid concentration is less than 0.05 µg/ml.

25 40. The device of claim 35, for use as in treatment or prevention for a disease state selected from ocular neovascularization, ocular inflammation, retinal degeneration, and retinopathy.

41. The device of claim 35, for delivering said corticosteroid(s) to the retina, retinal  
30 pigment epithelium (RPE) or choroids of the eye.

42. The device of claim 35, wherein said corticosteroid is selected from triamcinolone, dexamethasone, cortisone, prednisolone, flumetholone, and derivatives thereof.
- 5 43. The device of claim 35, wherein said corticosteroid is fluocinolone.
44. The device of claim 35, wherein said corticosteroid is fluocinolone acetonide.
45. The device of claim 35, wherein said corticosteroid is loteprednol.
- 10 46. The device of claim 38, wherein said corticosteroid is fluocinolone.
47. The device of claim 38, wherein said corticosteroid is fluocinolone acetonide.
- 15 48. The device of claim 38, wherein said corticosteroid is loteprednol.
49. The device of claim 40, wherein said corticosteroid is fluocinolone.
50. The device of claim 40, wherein said corticosteroid is fluocinolone acetonide.
- 20 51. The device of claim 40, wherein said corticosteroid is loteprednol.
52. The device of claim 35, wherein release of said corticosteroid(s) from said device follows zero order kinetics for at least 100 days.
- 25 53. The device of claim 35, having a mean release rate for said corticosteroid(s) of 1 µg/day to 50 µg/day.
54. The device of claim 35, having a mean release rate for said corticosteroid(s) of 1 µg/day to 10 µg/day.
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55. The device of claim 35, wherein said constant release of said corticosteroid(s) includes a linear release of said corticosteroid(s) for at least 100 days.
56. The device of claim 35, wherein said device releases said corticosteroid(s) for 1  
5 month to about 20 years.
57. The device of claim 35, wherein said device releases said corticosteroid(s) for 6 months to 5 years.
- 10 58. The device of claim 35, wherein said permeable coating(s) comprises a polymer coating selected from polyvinyl alcohols; polyolefins; polyvinyl chlorides; cross-linked gelatins; insoluble, non-erodible cellulose; polyurethanes; polycarbonates; and microporous polymers formed by co-precipitation of a polycation and a polyanion modified insoluble collagen.
- 15 59. The device of claim 35, wherein said permeable coating(s) comprises polyvinyl alcohol.
60. The device of claim 35, wherein said impermeable coating comprises ethylene  
20 vinyl acetate.
61. The device of claim 35, wherein said impermeable coating comprises polyvinyl acetate.
- 25 62. The device of claim 35, wherein said permeable coating(s) comprises polyimide.
63. The device of claim 35, wherein said impermeable coating comprises a silicone polymer.
- 30 64. The device of claim 35, wherein said pores in said impermeable coating of said device are less than 25 % of the surface area.

65. The device of claim 35, wherein said pores in said impermeable coating are less than 5 % of the surface area.

5 66. The device of claim 35, wherein said pores in said impermeable coating are less than 1 % of the surface area.

67. The method of claim 1, wherein said device maintains therapeutic concentration of said corticosteroid(s) in the eye for 1 month to about 20 years.

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68. The method of claim 1, wherein said device maintains therapeutic concentration of said corticosteroid(s) in the eye for 6 months to 5 years.

15 69. The device of claim 35, wherein said device maintains therapeutic concentration of said corticosteroid(s) in the eye for 1 month to about 20 years.

70. The device of claim 35, wherein said device maintains therapeutic concentration of said corticosteroid(s) in the eye for 6 months to 5 years.